

the ordinary types of scours in hogs; it would not be effective for a rundown condition in sows and for slow growing unthrifty pigs; and it would not be an effective remedy for "necro."

Black-Hawk's Special Dairy Products. Misbranding, Section 502 (a), certain statements contained in accompanying circulars entitled "Maximum Gain By Feeding Black Hawk Special Mineral Feeds" were false and misleading. The statements represented and suggested that the article would be an effective treatment and preventive for shy breeding, anemia, and lump jaw. The article would not be an effective treatment and preventive for such conditions.

DISPOSITION: September 17, 1953. Pleas of guilty having been entered, the court fined the corporation \$500, plus costs, and the individual \$20.

4180. Misbranding of calf medicine, cow capsules, and Laxotone. U. S. v. 239 Packages, etc. (F. D. C. No. 35205. Sample Nos. 41045-L to 41047-L, incl.)

LABEL FILED: May 4, 1953, Eastern District of Washington.

ALLEGED SHIPMENT: On or about November 12 and December 10, 1952, by Dr. David Roberts Veterinary Co., from Waukesha, Wis.

PRODUCT: 170 4-ounce packages and 69 10-ounce packages of *calf medicine*, 18 packages of *cow capsules*, and 60 3½-ounce packages and 22 10-ounce packages of *Laxotone* at Spokane, Wash., together with a number of booklets entitled "The Practical Home Veterinarian by Dr. David Roberts, D. V. S." and "The New Cattle Specialist" and a number of leaflets entitled "Take Good Care of Your Livestock and Your Livestock Will Take Care of You."

LABEL, IN PART: (Package) "Calf Medicine For Loose Bowels * * * Ingredients: Sulfathiazole, Salol, Bismuth Subnitrate, Ginger Root, Tannic Acid, Nicotine, White Oak Bark, Anise, Chalk, Sulphocarbolates of Calcium, Sodium, Zinc, Yeast Meal," "Dr. David Roberts' Cow Capsule Ant-Acid Ingredients: Wheat Germ Oil, Brewers Yeast, Bicarbonate of Soda, Sugar," and "Dr. David Roberts Laxotone Ingredients: Nux Vomica (Strychnine 2.515 grs. in each ounce), Anise, Cascarin, Licorice, Poke Root, Burdock Root, Fennel, Ginger, Jalap, Aloes, Sugar, Senna."

NATURE OF CHARGE: *Calf medicine.* Misbranding, Section 502 (a), certain statements in the labeling, namely, the package label and the above-mentioned booklets and leaflets accompanying the article, were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for diarrhea in cattle, horses, and swine; for calf scours, loose bowels of all livestock, and bowel disorders; and for scours in lambs when administered to the ewes. The article was not an adequate and effective treatment for such conditions and purposes. Further misbranding, Section 502 (a), the label statement "Ingredients: Sulfathiazole, Salol, Bismuth Subnitrate" was misleading in that the statement represented and suggested that sulfathiazole, salol, and bismuth subnitrate were present in the article in such proportions as to be of therapeutic significance when administered as directed, whereas such was not the case. (Analysis showed that the article contained, per tablespoonful, approximately 32 milligrams of sulfathiazole, 80 milligrams of salol, and 98 milligrams of bismuth subnitrate.)

Cow capsules. Misbranding, Section 502 (a), certain statements in the labeling of the article, namely, the package label and the above-mentioned booklets accompanying the article, were false and misleading. The statements represented and suggested that the article was of value in connection with

the breeding of cows and that it was an adequate and effective treatment for slow breeding in cows and failure to conceive. The article was not of value in connection with the breeding of cows, and it was not an adequate and effective treatment for the purposes represented.

Laxotone. Misbranding, Section 502 (a), certain statements in the labeling of the article, namely, the above-mentioned booklets and leaflets accompanying the article, were false and misleading. The statements represented and suggested that the article would keep the bowels in a normal condition, overcome the congestion associated with choking, keep the bowels regular, move the bowels naturally, and would act as a general stimulant, and that the article was an adequate and effective treatment for grass staggers, paralysis of the hind parts, red water in cattle, suppression of milk, fever, rheumatism in swine, sick cows, many disorders especially of cattle, bowel stoppage, bowel inaction and paralysis, azoturia, colic, impaction of bowels, bloating, diarrhea, and mastitis. The article was not an adequate and effective treatment for such conditions, and it was not capable of fulfilling the promises of benefit made for it.

DISPOSITION: July 31, 1953. Default decree of condemnation. The court ordered that the actual physical destruction of the products should be postponed for a period of 30 days to give the shipper an opportunity to submit proper labels for the products. The products and their labeling were destroyed on September 2, 1953.

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PRODUCTS

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AAC Compound tablets-----	4167	Diaphragms, vaginal-----	4165
Adroxal-----	4171	Gout, remedy for. <i>See</i> Rheumatism, remedy for.	
Alfalfa leaves, alfalfa seed, alfalfa seed tea, and alfalfa tablets-----	4169	Hog liquid, Ironated-----	4179
Alfa-Mint leaves-----	4169	Ironated Hog Liquid-----	4179
Alfamint tablets-----	4169	Lanolin, Mentos medicated-----	4175
Amphetamine, dextro-, sulfate tablets-----	4161, 4162	Laxotone-----	4180
Arthritis, remedy for. <i>See</i> Rheumatism, remedy for.		Liver injection-----	4166
Black Hawk's Special Dairy Products-----	4179	Lumax-----	4171
Blue Ridge Mountain Minerals--	4174	Lusalfa tonic-----	4170
Bursitis, remedy for. <i>See</i> Rheumatism, remedy for.		Master violet ray outfit-----	4178
Calf medicine-----	4180	Mentos medicated lanolin-----	4175
Clinical thermometers-----	4168	Neuralgia, remedy for. <i>See</i> Rheumatism, remedy for.	
Compressed tablets-----	4167	Neuritis, remedy for. <i>See</i> Rheumatism, remedy for.	
Cosmetic (subject to the drug provisions of the Act)-----	4175	Pads, Rado-----	4177
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Dextro-amphetamine sulfate tablets-----	4161, 4162	Rado pads-----	4177
		Rejuvenator-----	4164
		Rheumatism, remedy for (de-vice)-----	4177
		Sciatica, remedy for. <i>See</i> Rheumatism, remedy for.	

U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

4181-4200

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare, and include, where indicated, the results of investigations by the Department, prior to the institution of the proceedings. Published by direction of the Secretary of Health, Education, and Welfare.

CHARLES W. CRAWFORD, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *July 19, 1954.*

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*For omission of, or unsatisfactory, ingredients statements, see Nos. 4187, 4188; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 4187, 4188; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 4187, 4188, 4190.

**DRUG ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED
ACCORDING TO DIRECTIONS**

4181. Misbranding of Special Formula cream. U. S. v. 8 Jars * * *. (F. D. C. No. 35320. Sample No. 58957-L.)

LIBEL FILED: June 22, 1953, Western District of Michigan.

ALLEGED SHIPMENT: On or about March 31, 1952, by Bette Knowlton, from Miami, Fla.

PRODUCT: 8 jars of *Special Formula cream* at Grand Rapids, Mich. Examination showed that the article contained estrogenic hormones equivalent to 54,000 International Units (5.4 mg.) of estrone per ounce.

RESULTS OF INVESTIGATION: On or about March 23, 1952, the consignee received at Miami, Fla., from the Bette Knowlton Laboratories, a 26-page mimeographed booklet dated May 14, 1951, entitled "Bette Knowlton Reference Manual," to be used in the sale and use of the Bette Knowlton products. This booklet subsequently was transported by the consignee from Miami, Fla., to Grand Rapids, Mich. In addition, Bette Knowlton shipped from Miami, Fla., to Grand Rapids, Mich., on or about February 1, 1953, a number of leaflets entitled "Bette Knowlton Fortune In Loveliness" and one booklet entitled "Bette Knowlton Reference Notes."

LABEL, IN PART: (Jar) "Bette Knowlton Special Formula Cream 2 Oz. * * * Hormone & Vitamin A Formula. Contains Type A Natural Extrogenic Substance, 50,000 I. U. per oz., and Vitamin A, 10,000 units per oz."

NATURE OF CHARGE: Misbranding, Section 502 (j), the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling, namely, the jar label and the above-mentioned leaflets and booklets, since the labeling provided for the daily application of 1,800 International Units of estrogens as estrone over an extended and indefinite period of time, an amount which would cause injury to health.

DISPOSITION: July 9, 1953. Default decree of condemnation and destruction.

NEW DRUG SHIPPED WITHOUT EFFECTIVE APPLICATION

4182. Pyrilamine maleate-dextro-amphetamine sulfate. U. S. v. 187 Cartoned Vials * * *. (F. D. C. No. 35259. Sample No. 70469-L.)

LIBEL FILED: May 13, 1953, Northern District of Ohio.

ALLEGED SHIPMENT: On or about February 13, 1953, by Addison Laboratories, from Philadelphia, Pa.

PRODUCT: 187 cartonated vials of *pyrilamine maleate-dextro-amphetamine sulfate* at Mansfield, Ohio. Analysis showed that the product contained essentially the amount of pyrilamine maleate stated on its label and 0.5 percent of phenol.

LABEL, IN PART: (Vial) "10 cc. Multiple-Dose Vial List No.: 1059 Pyrilamine Maleate-Dextro Amphetamine Sulphate Each cc. contains: Pyranisamine maleate 25 mg., Dextro Amphetamine Sulphate 2 mg."

NATURE OF CHARGE: Section 505 (a), the article was a new drug within the meaning of the law, and an application filed pursuant to the law was not effective with respect to the article.

DISPOSITION: June 11, 1953. Default decree of condemnation and destruction.